

Package leaflet: Information for the user

Terbinafine

Hydrochloride 1% cream

Terbinafine hydrochloride



Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Terbinafine Hydrochloride 1% cream (hereafter Terbinafine cream) is and what it is used for
2. What you need to know before you use Terbinafine cream
3. How to use Terbinafine cream
4. Possible side effects
5. How to store Terbinafine cream
6. Contents of the pack and other information

1. What Terbinafine cream is and what it is used for

Terbinafine cream is an anti-fungal preparation. It kills fungi, which cause skin infections. Terbinafine cream is used for the local treatment of fungal infections of the skin.

2. What you need to know before you use Terbinafine cream

Do not use Terbinafine cream

- if you are allergic to terbinafine or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using Terbinafine cream.

Terbinafine cream is for external use only.

Avoid contact of the cream with your eyes. If it gets into the eyes accidentally, the eyes should be rinsed thoroughly with running water and you should consult an ophthalmologist if necessary.

Before and after application you should always wash your hands.

Terbinafine cream should be kept out of the sight and reach of children.

Children

The use of Terbinafine cream is not recommended for children.

Other medicines and Terbinafine cream

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

There are no known drug interactions of Terbinafine cream with other medicinal product.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Terbinafine cream should not be used during pregnancy unless you are advised to do so by your doctor. Your doctor will decide if the potential benefits outweigh any potential risks.

Terbinafine passes into breast milk; therefore, it should not be used during breast-feeding. Infants must not be allowed to come into contact with any treated skin, including the breast.

Driving and using machines

Terbinafine cream has no influence on the ability to drive and use machines.

Terbinafine cream contains cetyl alcohol, cetostearyl alcohol and benzyl alcohol

Cetyl alcohol and cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis). Benzyl alcohol may cause mild local irritation.

3. How to use Terbinafine cream

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will decide the right amount of Terbinafine cream for you to use and will tell you how long to use your medicine. Follow your doctor's instructions exactly.

For application to the skin only.

Terbinafine cream is usually applied once or twice daily. The cream is generally used for 1 to 2 weeks, but this will depend upon the type and area of infection. Make sure that you have cleaned and dried the affected skin and surrounding areas thoroughly before applying Terbinafine cream in a thin layer. The cream should be rubbed in gently and the affected areas may be covered with a gauze dressing, especially at night. You should exchange the gauze strip for a new and clean one after each and every application of the cream.

The treatment should be continued for one week in case of tinea pedis (fungal infection affecting the feet) and in other cases (e.g. pityriasis versicolor: a rash caused by a yeast-like germ called Malassezia) for two weeks.

Treatment should be continued for the recommended period of time even if the damaged skin area seems to be healed earlier. Thus, you could avoid re-infection and promote a successful treatment.

If there are no signs of improvement after two weeks of treatment, consult your doctor.

If you forget to use Terbinafine cream

If you forget to use your cream, apply the cream as soon as possible, and then continue the rest of your treatment as usual.

If you use more Terbinafine cream than you should

In case of accidental ingestion of Terbinafine cream, headache, nausea, pain in the upper middle part of the abdomen and dizziness may be expected. If you or someone else including a child, accidentally swallowed the cream, contact your doctor immediately.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

In rare cases people may be allergic to Terbinafine cream, which could cause swelling of the tongue, throat, face and lips, difficulty breathing or swallowing as well as blistering, severe skin rash, hives or a worsening of itch. If you experience any of these particular symptoms, *stop using Terbinafine cream and tell your doctor or pharmacist immediately.*

Local symptoms listed below may occur at the site of application. These are harmless and usually you can continue the treatment.

Common (may affect up to 1 in 10 people) side effects:

- Peeling skin, itching of the skin

Uncommon (may affect up to 1 in 100 people) side effects:

- Damage to the skin, scab, skin disorder, pigmentation disorder, redness of the skin (erythema), skin burning sensation
- Pain, application site pain, application site irritation

Rare (may affect up to 1 in 1,000 people) side effects:

- Eye irritation
- Dry skin, redness and swelling of the skin (contact dermatitis), eczema
- Worsening of the skin condition

Not known (frequency cannot be estimated from the available data) side effects:

- Rash

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Terbinafine cream

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Store in original container.

Do not use this medicine if you notice visible signs of deterioration.

If your doctor decides to stop your treatment, return any leftover medicine to the pharmacist. Only keep it if your doctor tells you to.

Discard any unused content one month after opening.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Terbinafine cream contains

- The active substance is terbinafine hydrochloride
- The other ingredients are sodium hydroxide, benzyl alcohol, sorbitan stearate, cetyl palmitate, cetyl alcohol, cetostearyl alcohol, polysorbate 60, isopropyl myristate, water purified.

What Terbinafine looks like and contents of the pack

White or almost white cream, with slight almond odour.

Packs contain 1 tube of cream (7.5 g, 15 g or 30 g)

Marketing Authorisation Holder and Manufacturer

Gedeon Richter Plc.
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This leaflet was last revised in August 2018



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GB 674-5236-APIL
RG 6052, K-8942-1.4, 29352250

